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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,963	01/28/2002	Andras Guttman	1360.038US1	4487

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JENKINS & WILSON, PA
3100 TOWER BLVD
SUITE 1400
DURHAM, NC 27707

EXAMINER	
STARSIAK, JOHN S	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,963	GUTTMAN ET AL.	
	Examiner	Art Unit	
	John S. Starsiak Jr.	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 to 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 to 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *30 April 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 24, 27, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Burd

The claims read on the operation of the embodiment of Burd illustrated in Figure 1. The "applying a sample" step recited in claim 21 reads on the function of sample reservoir 29. Specifically, Burd teaches [column 3, lines 41 to 43]: "A sample reservoir **29** is included in the block (**28**) for sample introduction.". The "generating a migratory field" step recited in claim 21 reads on function of cathode **15**, anode **16**, and power source **17**. Regarding the " eluting" step and "collecting" step recited in claim 21 and the "analyzing " step recited in claim 24, Burd teaches [column 1, lines 50 to 54]: "In the former, the segments are used to separate the species eluting from the larger capillary into *separate receptacles*, from which they may be separately recovered, *detected*, treated or otherwise processed.". Regarding the "interrupting the migratory field" step recited in claim 21, Burd teaches [column 4, lines 1 to 17]: "In the embodiment shown in FIG. **1,** it will be noted that the capillary segments **18** are spaced apart at intervals

around the cassette **12**. The external openings **40** of the adjacent capillary segments are separated by portions of solid external wall **41**. In the arrangement shown, these intervening wall portions close off the separation capillary **11** and *interrupt the current path* whenever the capillary segments **18** not in alignment between the separation capillary **11** and the outlet buffer reservoir **14**. With the current path interrupted in this manner, the electrophoretic migration of solute species within the separation capillary **20** as well as all other portions of the apparatus is momentarily suspended while the cassette rotates further and brings the next capillary segment into position. Thus, no components of the sample are lost and the entire elution profile will be distributed among the various capillary segments in the cassette.". The "collecting" step recited in claim 21 includes the limitation "without using a detector to analyze the analyte prior to collection". While the embodiment illustrated in Figure 1 shows a detector for analyzing the separated species prior to elution, this is an optional feature. Burd teaches [column 4, lines 59 to 61]: "A variety of additional features *may* be incorporated into either of these systems. On-line detection, for example, *may* be achieved...". The "repeating" step recited in claim 21 reads on Burd [column 1, line 41-43]: "The process may be repeated in an extended sequence, or as few times as once.". The limitation recited in claim 24 reads on Burd [column 1, lines 46 to 54]: "The invention has two primary embodiments, one in which the interchangeable segments are positioned at the downstream end of the larger, main body of the capillary,....the segments are used to separate the species into separate receptacles, from which they may be separately recovered, *detected*, treated or otherwise processed.". The limitations recited in claims

27 and 30 read on Burd [claim 14, lines 14 to 21]: "(c) moving said first and second structural members with respect to each other to place said capillary segments one at a time in alignment with said separation capillary; and (d) upon alignment of each of said capillary segment with said separation capillary, imposing an electrical potential across the combined lengths of said separation capillary and the capillary segment aligned therewith.". The limitation recited in claim 31 reads on Burd since the completely removing the electrical potential within the separation pathway constitutes "adjusting a potential within the separation pathway".

Claims 21-27 and 30-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Strausbauch et al.

The "applying a sample" step, the "generating a migratory field" step, the "eluting an analyte" step and the "collecting the analyte" step recited in claim 21 and the limitation recited in claim 27 read on Strausbauch et al. because these steps occur in any preparative capillary electrophoretic separation" e.g. [page 842, lines 19to 21]: "The low volume of a sample injection, requirement for fraction collection, and the unavoidable presence of high voltage (10-30 kV)". Regarding the "interrupting" step recited in claim 21 and the "positioning" limitation recited in claim 30, Strausbauch et al. teaches [page 846, lines 1 to 7]: "The collection can be performed by manually changing the outlet (collection) vial at predetermined intervals with the applied voltage interrupted while either the outlet vial or capillary outlet is repositioned for each fraction. Because the electrophoresis buffer in the vial usually completes the high voltage circuit between the capillary and the outlet electrode, the operator may be exposed to a

potential shock hazard. A preferred variation of the method is to have an automated fraction collector manipulate the outlet vials or capillary/outlet electrode assembly. Although Strausbauch et al. does not explicitly state "collecting the analyte in a collection well without the using a detector to analyze the analyte prior to collection" (i.e., absence of an on-column detector), Strausbauch et al. does teach [page 849, lines 8 to 12]: "Fraction collection routines can be programmed to collect a single component "window" when the peak of interest and migration characteristics are known. Alternatively, fractions can be collected at fixed time intervals to collect the entire electrophoretic separation for recovery and assay of unknowns". Neither of these methods would require an on-column detector. The "applying a sample" step and "generating a migratory field" step are inherent in any capillary electrophoretic separation. The limitations recited in claims 22 and 24 clearly read on the second method of Strausbauch et al. above. The limitation recited claims 23 and 32 clearly read on the first method of Strausbauch et al. above. Claim 31 reads on Strausbauch et al. since complete removal of the potential from the capillary (zero potential) constitutes an adjustment of the potential in the capillary. Regarding claims 25 and 26 see the section of Strausbauch et al. titled "Micro-Preparative CE of Nucleic Acids" and the section of Strausbauch et al. titled "Micro-Preparative CE of Peptides and Proteins".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lunte et al. in view of Burd or Strausbauch et al.

All of the method steps recited on claim 21 read on the operation of the apparatus of Lunte et al. illustrated in Figure 3. except for the "interrupting" step. While the "applying" step and "generating" step recited in claim 21 may not be explicitly recited in Lunte, they read on Lunte et al. because these steps occur in any capillary electrophoresis separation". The "collecting" step and "repeating" step are not explicitly recited in Lunte et al. these steps clearly read on the operation of the embodiment of Lunte et al. illustrated in Figure 3. The limitation that the collection occurs "without

using a detector to analyze the analyte prior to collection" recited in claim 21 reads on Lunte et al. [column 2, lines 26 to 32]: "Broadly speaking, the CE apparatus hereof includes an elongated electrophoretic capillary tube assembly of length (e.g., 1 meter) required for the separation of interest. One end of the tube is designed for connection with a power supply for applying a high voltage across the tube assembly; the opposite end of the tube assembly is adapted for coupling to an appropriate CE detector." and the fact that the embodiment illustrated in Figure 3, lacks an on-column detector. Lunte et al. is silent concerning interrupting the "migratory field" while one collection vial is exchanged for another. It is notoriously well known in the capillary electrophoresis art to temporary interrupt the electric field when exchanging one collection vial for another. Burd and Strausbauch et al. are two of many references which disclose this teaching. Hence it would have been obvious to one of ordinary skill at the time of the invention to interrupt the electric filed through the capillary of Lunte et al. when changing collection vials because this would prevent to lose of any of the separated species during the exchange of collection vials.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd or Strausbauch et al in view of Karger et al.

Regarding the teachings of Burd and Stausbauch et al. see the rejections based on these references above. Karger et al. is similar to Burd and Strausbauch et al. in that the detailed embodiment of Karger et al is directed to capillary electrophoresis including fraction collection. However, Karger teaches [page 5, lines 20 to 30]: "The system of the

invention will now be described in detail using as an example a system for the separation of fluorescently labeled DNA fragments by capillary electrophoresis;....Any method of separation could be employed , including but not limited to capillary electrophoresis (CE).....and *capillary liquid chromatography*(CLC). Capillary liquid chromatography involves creating a pressure differential between the ends of the capillary. This differential can be created by collecting one end of the capillary to either a source of pressure above ambient pressure ("applying a pressure to the separation pathway") or a source of pressure below ambient pressure ("drawing a vacuum in the separation pathway"). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods of Burd or Strausbauch et al. for fraction collection in capillary liquid chromatography even though the disclosure of Burd or Strausbauch et al. explicitly disclose capillary electrophoresis because Karger et al. teaches that this is within the abilities of one skilled in the art.

Response to Arguments

Applicant's arguments with respect to claims 21-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (571)

272-1346. The examiner can normally be reached on Monday to Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

John S. Starsiak Jr.

21 July 2004

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700